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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Comparability Studies for Human Plasma-Derived Therapeutics; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the Plasma Protein Therapeutics Association (PPTA), entitled "Comparability Studies for Human Plasma-Derived Therapeutics." The workshop will discuss current guidance, critical issues, and approaches for establishing the comparability of human plasma derivatives in order to support changes in manufacturing processes, equipment, or facilities.

Date and Time: The public workshop will be held on May 30, 2002, from 8 a.m. to 5:30 p.m., and on May 31, 2002, from 9 a.m. to 12 noon.

Location: The workshop will be held at the Doubletree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact: HelmsBriscoe Resource One, 12530 Browns Ferry Rd., Herndon, VA 20170, 703–421–5826, FAX 703–444–1737.

Registration: Preregistration is recommended on or before May 29, 2002. Onsite registration will be done on a space-available basis on both days of the workshop, beginning at 7:30 a.m. You may obtain registration forms and information about registration fees from HelmsBriscoe Resource One (see the *Contact* section of this document) or from Joseph Wilczek, Project Manager,

at wilczek@cber.fda.gov. Mail or fax your registration information and registration fee to HelmsBriscoe Resource One by May 29, 2002.

If you need special accommodations due to a disability, please contact HelmsBriscoe Resource One at least 7 days in advance.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The public workshop transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

SUPPLEMENTARY INFORMATION: FDA and PPTA are jointly cosponsoring a public workshop on comparability studies for human plasma-derived therapeutics. The workshop will discuss critical issues and approaches for establishing the comparability of human plasma derivatives for supporting changes in manufacturing processes, equipment, or facilities. On May 30, 2002, the workshop will address the three levels of comparability studies—physical/chemical characterization, preclinical studies, and clinical evaluations as they are related to manufacturing changes for a human plasma derivative, as well as information on reporting manufacturing changes, comparability protocols, and several case studies.

On May 31, 2002, the workshop will focus on issues related to comparing fractionation intermediates, a topic specific to the plasma derivative industry. FDA will present historical perspectives and current guidance on cooperative manufacturing arrangements. Industry will discuss the current status of the necessity for fractionation intermediates from sources outside of the company and the criteria for acceptance. The complexities involved in characterizing

the source material, intermediates, and the drug products will be discussed. The public workshop agenda will be posted on the Internet at http://www.fda.gov/cber/whatsnew.htm.

Dated: 4/29/02

April 29, 2002.

Margaret M. Dotzel

Margaret M. Dotzel,
Associate Commissioner for Policy.

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